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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087486,070	06/07/95	STAVRIANOFIDLOS	J ENZ-7(P)(C3)

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18M2/0121

EXAMINER
MARSCHEL, A

ART UNIT
1807

PAPER NUMBER

DATE MAILED:

~~01/21/98~~

4/9/98

Pl ase find below.and/or attached an Office communication concerning this application or proceeding.

Commisssloner of Patents and Trademarks

Office Action Summary

Application No.
08/486,070

Applicant(s)
Stavrianopoulos et al.

Examiner
Marschel, Ardin

Group Art Unit
1807



☒ Responsive to communication(s) filed on May 14, 1996

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 48-132 is/are pending in the application.

~~Of the above, claim(s) 1-47 have been canceled.~~ ~~Claims withdrawn from consideration.~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 48-132 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

It is acknowledged that the Petition to revive the instant application has been granted as given in the communication, mailed 8/1/97.

Applicants' arguments; filed 5/14/96, have been fully considered but they are not deemed to be persuasive to overcome the rejections set forth in the previous office action, mailed 10/2/95. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 53, 54, 60, 63, 77-99, 101, 107, 108, 114, and 118 are rejected, as discussed below, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 53, 78, and 107 contain NEW MATTER in that "siliceous matter" is cited. Consideration of the instant disclosure as filed has failed to reveal written basis for this phrase. It is noted that glass is disclosed as filed but not the broader phrase "siliceous matter". This broadening in scope is NEW MATTER. Similarly, claims 54, 79, and 108 contain the phrase "glass-coated surface" which lacks written basis as filed.

Claims 63, 86, and 118 contain NEW MATTER because there is

no written basis as filed for either DNA-RNA hybrid or a DNA-RNA chimera.

Consideration of the disclosure as filed has failed to reveal the limitation of instant claims 60 and 114 directed to the support and system being composed of different materials. This limitation is therefore NEW MATTER.

Claims 77-85 and 87-99 contain NEW MATTER because the oligonucleotide or polynucleotide is cited as fixed or immobilized to the system rather than being limited to being fixed or immobilized to the solid support within such a system. Consideration of the disclosure as filed has not revealed fixing or immobilizing to a system as now cited in claims 77 etc.

Claim 101 cites the phrase "instructions therefor" in the last line. Consideration of the disclosure as filed has failed to reveal written basis for any such instructions which therefore causes claim 101 to contain NEW MATTER.

The above NEW MATTER rejections are either reiterated or necessitated by amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 48-50, 53-56, 59, 61, 63-81, 84, 86-100, 102-104, 107-109, 113, and 115-132 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kourilsky et al. (UK 2,019,408).

Kourilsky et al. disclose the preparation of various probes which hybridize to target nucleic acid on page 3. In particular cytochrome C is utilized to attach biotin to a probe. Beta-galactosidase is linked to the hybridized probe via avidin which is then centrifuged as given on said page 3, lines 42-49. Centrifuge tubes are inherently either glass or plastic. The pellet from this centrifugation is the practice of at least temporarily fixing the probe with enzymatic label onto a solid support device or system. The pellet is resuspended and optically assayed in solution for the enzymatic activity of the beta-galactosidase. This reads on the instant claims.

Applicants argue the below art rejections in that the practice of in-situ hybridization is a very specialized type of methodology and different from the soluble signal generation practice as instantly claimed. In response applicants are reminded that compositions, apparatus, and systems are claimed and not methods. Therefore, if a reference meets the composition, apparatus, or system limitations, it anticipates the instant invention even if a number of uses can be practiced for the claimed invention. In other words patentable weight is not given to use limitations if they do not limit the actual composition etc. limitations.

Claims 48-54, 56, 59, 61-79, 84-100, 102-108, 113, and 115-132 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Stuart et al.

Applicants argue that Stuart et al. is concerned with in situ hybridization and not applicable. This is non-persuasive as already discussed above. Applicants then argue that the instant invention requires chemically labeled nucleic acid for one of the strands. This is also non-persuasive because there is therein no limitation regarding whether a label may or may not also interact with the second strand in a hybrid formed during a hybridization assay. This rejection is reiterated and necessitated by amendment due to the newly added claims.

Claims 48-54, 56, 59, 61-79, 84-100, 102-108, 113, and 115-132 are rejected under 35 U.S.C. § 102(a) as being clearly

anticipated either by Langer-Safer et al. or Manuelidis et al.

The listed claims are anticipated either by Langer-Safer et al. or Manuelidis et al. in the same manner as the above rejection based on Stuart et al. because both references also discussed the performance of in situ hybridization of chromosome spreads on microscope slides etc. as summarized above. This rejection is reiterated and necessitated by amendment due to the newly added claims.

Claims 48-132 are rejected under 35 U.S.C. § 102(e) as being anticipated by Ward et al.

Ward et al. disclose via the "GENERAL PROTOCOL" and with connected discussion elsewhere at the bottom of columns 19 and 20 in situ hybridization where immobilized double-stranded nucleic acid is shown visualized with a biotinylated probe bound to avidin-peroxidase. This reads on the listed claims as the peroxidase is capable of generating a soluble signal as discussed above and therefore still reads on the instant invention even though Ward et al. discloses insoluble signal generation. This rejection is reiterated and necessitated by amendment due to the newly added claims.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*,

759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-132 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of U.S. Patent No. 4,994,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain common embodiments regarding devices, compositions, apparatus, and kits. It is noted that a terminal disclaimer was filed in the immediate parent to the instant application, however, when a new application serial number is utilized due to the instant application being a continuation of said parent a new terminal disclaimer must be filed.

The disclosure is objected to because of the following informalities:

The use of the trademark TRITON X-100 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. See, for example, page 24, lines 9-10, 22, and 30.

Although the use of trademarks is permissible in patent

applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

January 20, 1998

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800